NDA 022000-S23

SUPPLEMENT APPROVAL

Takeda Pharmaceuticals
Attention: Valerie Tews
Associate Director, Regulatory Strategy
95 Hayden Avenue
Lexington, MA 02421

Dear Ms. Tews:

Please refer to your supplemental new drug application (sNDA) dated September 2, 2021, received and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lialda (mesalamine) delayed-release tablets.

We also refer to our letter dated August 3, 2021 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for aminosalicylic acid and similar agents. This information pertains to the risk of severe cutaneous adverse reactions (SCARs), which includes Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP), reported in FAERS.

This supplemental new drug application provides for revisions to the labeling for Lialda, consistent with our August 3, 2021 letter.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter with minor editorial revisions listed below and reflected in the enclosed labeling:

- Highlights of the Prescribing Information: relocated the heading for Warnings and Precautions to the top of the second column.
- Remove "/" before "SJS/TEN" in Section 6.2 Postmarketing Experience in the Full Prescribing Information.

We note that your October 26, 2021, submission includes final printed labeling (FPL) for your Prescribing Information, Patient Package Insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this FPL is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions, call Kelly Richards, Regulatory Project Manager, at (240) 402-4276.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology (DG)
Office of Immunology and Inflammation (OII)
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOYCE A KORVICK
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